UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

RANDALL HIX, *et al.,*

Plaintiffs,

v.

ZIMMER BIOMET HOLDINGS, INC, *et al*.,

Defendants.

Case No. 3:18-cv-00437-RCJ-WGC

ORDER

In 2010, Randall Hix had an artificial hip replacement using a Biomet M2a Magnum implant. Hix and his wife, Liana Hix, brought this suit against Defendants Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC, (collectively "Biomet") alleging the artificial hip device was defective. (Amended Complaint, ECF No. 201). Presently before the Court is Biomet's motion to exclude Richard Blakey, M.D., Hix's treating physician. (ECF No. 274). Hix opposes the motion. (ECF No. 284). The Court will deny the motion.

I. PROCEDURAL HISTORY

On October 2, 2012, the Judicial Panel on Multidistrict Litigation transferred the first actions regarding Biomet M2a Magnum hip implants to the Northern District of Indiana as the Biomet M2a Magnum Hip Implants Products Liability multi-district litigation, MDL Case No. 3-12-md-2391. In February 2013, the MDL court entered an order allowing parties to file new actions directly into the MDL action. In March 2014, Hix initiated this action by filing a complaint in the Biomet M2a

Magnum MDL. Following consolidated pre-trial proceedings, the MDL court transferred this matter to the District of Nevada in September 2018.

II. BACKGROUND

On July 12, 2010, Hix (then 36 years old) had a total hip arthroplasty (THA, i.e., joint replacement) performed by Dr. Richard Mullins. Dr. Mullins implanted the Biomet M2a Magnum metal-on-metal (MoM) artificial hip device.

Prior to the THA procedure, Hix had surgery in 1997 on his left hip due to a Slipped Capital Femoral Epiphysis when he was 13 years old.

In 2008, Hix began experiencing pain in his left hip that worsened over time. In March 2010, Hix was arthroscopically treated for left hip femoroacetabular impingement. When the procedure did not resolve Hix's pain, he was referred to Dr. Mullins, who recommended a total left hip replacement. Hix and Dr. Mullins met with a Biomet sales representative who demonstrated Biomet's sample hip prosthetics. Dr. Mullins thought that a metal-on-metal device would provide Hix a better quality of life – and would last longer – than a metal-on-polyethylene device. Hix decided to have the M2a Magnum MoM device implanted.

Following the THA procedure, Hix began again experiencing pain in his left hip in March 2012. He saw Dr. Suzanne Zsikla, who referred Hix to Dr. Richard Blakey, an orthopedic surgeon. Hix saw Dr. Blakey in August 2012. A radiograph was taken, showing the MoM implant with reactive bone at the end of the stem. A presumptive diagnosis of metallosis[1] was made.

A bone scan performed on September 5, 2012, indicated Hix's hip was normal and did not indicate an abnormal uptake. On September 11, 2012, Dr. Blakey indicated he was fairly certain

[1] In his deposition, Hix's treating physician, Dr. Blakey, described metallosis as an inflammatory reaction to the wear product of an MoM device.

Hix did not have an infection and recommended a revision of the Biomet M2a Magnum MoM hip device.

Dr. Blakey performed the revision surgery on Hix's left hip on October 31, 2012. Dr. Blakey removed the Biomet acetabular cup and replaced it with a Zimmer metal-on-polyethylene constrained hip construct. He also removed damaged tissue and implanted a constrained liner to reduce the chance of dislocation or subluxation. Dr. Tony Yang examined the removed tissues for pathology and noted chronic inflammation, reactive hyperplasia, and pigmented macrophages containing a grayish pigment consistent with foreign material. Dr. Blakey's post-operative diagnosis noted painful left metal-on-metal total hip secondary to metallosis.

Two weeks after this surgery, Hix had an MRI of his lumbar spine, which showed an L5-S1 right-sided paracentral disc protrusion causing mild stenosis of the right neural foramina.

On January 10, 2013, Hix was seen by Dr. Blakey as Hix had "developed some cellulitis about the left hip wound." Dr. Blakey informed Hix that he might need to aspirate the hip. This procedure was performed on January 24, but produced "little fluid, if any." Cultures on the fluid were negative for infection. Hix was continuing to have pain when he had an office visit with Dr. Blakey in June 2013. Dr. Blakey "talked to [Hix] about the fact that sometimes the metallosis reaction comes back even though we have revised the hip." Dr. Blakey performed another left-hip aspiration in August 2013 and gave Hix a steroid injection.

Hix had a follow-up visit a week later. Dr. Blakey recorded in his notes: "I suspect that he is having continued inflammation, possibly from the metallosis." Following an office visit two weeks later, Dr. Blakey noted there was not much else he could do for Hix's pain.

Hix continued to have pain through 2014. In November 2014, Hix saw Dr. Martin Arraiz, who noted radiculitis (pain radiating along a nerve resulting from inflammation at the root of the

nerve connecting to the spine) in the lower left extremity. Hix received an epidural injection in December 2014.

Hix saw Dr. Blakey in January 2015. Dr. Blakey noted Hix "is actually getting better with respect to his left hip. He is still having pain." Following a July 2015 office visit, Dr. Blakey noted "Hix has had increasing pain in his left hip revision last month."

On October 21, 2017, Hix went to the emergency room the day following "kicking an object . . . with his left leg" that resulted in "sudden onset pain left hip." The emergency doctor noted a final impression of "[p]ain of left hip joint" and "[d]islocation of left hip."

Two days later, Dr. Chad Watts performed a revision surgery on Hix's left hip for "failed constrained liner with dislocation of left total hip." Dr. Watts removed the cup with constrained liner and replaced it with a "62 Biomet OsseoTi shell with dual mobility liner" and "2B +6 revision ceramic head with a titanium sleeve." Dr. Watts notes indicate that Hix "was very scarred in and had a pretty stiff hip. There was some metal staining from his prior metallosis, but overall the muscle and tissues were in reasonable shape." He further noted the "constrained liner was broken – there had clearly been chronic impingement which led to failure."

Four weeks after the surgery, Hix visited the emergency room with "pain to the surgical site, redness, and drainage around surgical incision associated with fever (102.0 deg F) and chills." Hix underwent surgery the following day to open the surgical wound for "drainage with debridement and placement of wound VAC." Two days later, Dr. Robert Crouse performed another surgery. As Hix had "an obvious deep infection," Dr. Crouse removed the artificial hip devices, removed infected material for biopsy and culture, and performed a femoral osteotomy. Dr. Crouse further placed an antibiotic impregnated cement spacer in the acetabulum, the location of the infection. The material removed for culture showed growth for Staphylococcus lugdunensis, with 1 of 3 cultures showing

growth for Methicillin-Resistant Staphylococcus aureus. Hix remained on IV antibiotics for six weeks.

On February 8, 2018, Dr. Watts implanted an artificial hip consisting of a Stryker Restoration cup and stem with a ceramic head and cable.

Hix had an office visit with Dr. Ali Nairizi in June 2018 for pain management. Over the following year, Hix underwent a femoral nerve block, lumbar sympathetic nerve block, and SI joint injections with corticosteroids for pain.

In September 2019, Dr. Denis Patterson implanted a temporary dorsal root ganglion spinal cord stimulator for pain management and implanted a permanent stimulator the next month.

In November, Hix had an office visit with Dr. Watts, reporting a significant increase in pain and redness and swelling around the left hip. Dr. Watts recorded the impression of "[l]ikely infected left hip replacement." Dr. Watts aspirated the left hip. A culture of the withdrawn material indicated a streptococcus viridans infection. Hix underwent surgery on his left hip the following day, with Dr. Watts performing a tissue debridement and irrigation, and exchanging the MDM liner, the ceramic head and MDM head. On December 1, 2019, Dr. Watts performed another debridement and irrigation of the hip. Hix was hospitalized for the infected left hip from November 22, through December 11, 2019.

In May 2020, Dr. Patterson exchanged the implantable power generator for the nerve stimulator.

III. LEGAL STANDARDS

A. Admissibility of Expert Testimony

Federal Rule of Evidence 702 governs the admission of expert testimony and provides that if a witness is qualified as an expert by knowledge, skill, experience, training, or education, the witness can provide opinion testimony so long as:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The task of the trial court is to "assure that the expert testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" *Primiano v. Cook,* 598 F.3d 558, 564 (9th Cir. 2010) *quoting Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 597 (1993). This task applies to all expert testimony governed by Rule 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-148 (1999). Rule 702 "is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of [the relevant] discipline." *Daubert*, 509 U.S. at 592. The party offering the expert witness "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." Fed. R. Evid. 702 Advisory Committee Notes.

"[M]any factors will bear on the inquiry." *Daubert*, 509 U.S. at 593. In considering the admissibility of scientific expert testimony, the Supreme Court generally noted four factors while acknowledging that it was not setting "out a definitive checklist or test." *Id.* As summarized by the Ninth Circuit, a court may consider: "1) whether the theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error and the existence of standards controlling a technique's operation; and (4) whether or not the theory is generally accepted." *United States v.Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000). However, these factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho*, 526 U.S. at 150.

Ultimately, the court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.7

B. Expert Disclosure and Report Requirements

Rule 26(a)(2) requires parties to "disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705." The Advisory Committee Notes to the 1993 amendments to Rule 26 indicate that the disclosure requirements for expert testimony were intended to allow opposing parties to have a reasonable opportunity to prepare for effective cross-examination and arrange for expert testimony from other witnesses. See Fed. R. Civ. P. 26 Advisory Comm. Notes (1993).

Experts who are retained or specially employed to give expert opinion testimony in a case are required to comply with the Rule 26(a)(2)(B) report requirements. For each such disclosed expert, Rule 26(a)(2)(B) requires that the expert witness disclosure be accompanied by a written report prepared and signed by the witness containing: (1) a complete statement of all opinions and the basis and reasons for them; (2) the facts or data considered by the witness in forming them; (3) any exhibits that will be used to summarize or support them; (4) the qualifications of the witness, including a list of all publications authored by the witness in the previous 10 years; (5) a list of all other cases in which the witness testified as an expert at trial or by deposition within the preceding 4 years; and (6) the compensation to be paid for the study and testimony. Fed. R. Civ. P. 26(a)(2)(B). An expert's report must be "detailed and complete." *Elgas v. Colorado Belle Corp.*, 179 F.R.D. 296, 300 (D. Nev. 1998) (quoting *Sierra Club v. Cedar Point Oil Co., Inc.*, 73 F.3d 546, 571 (5th Cir. 1996)). Expert reports are required to eliminate "unfair surprise to the opposing party and [to conserve] resources." *Id.* at 299 (quoting *Reed v. Binder*, 165 F.R.D. 424, 429 (D.N.J. 1996)).

All other experts are required to comply with the expert disclosure requirements of Rule 26(a)(2)(C), which are considerably less extensive than the disclosure requirements of Rule 26(a)(2)(B). Rule 26(a)(2)(C) requires disclosure of "(i) the subject matter on which the written witness is expected to present evidence under Federal Evidence Rule 702, 703 or 705; and (ii) a summary of facts and opinions to which the witness is expected to testify." Fed. R. Civ. P. 26(a)(2)(C)(i), (ii). The disclosure obligation stated in 26(a)(2)(C) "does not apply to facts unrelated to the expert opinions the witness will present." Fed. R. Civ. P. 26 Advisory Comm. Notes (2010). The Advisory Committee Notes regarding Rule 26(a)(2)(C) state, in relevant part:

> Rule 26(a)(2)(C) is added to mandate summary disclosures of the opinions to be offered by expert witnesses who are not required to provide reports under Rule 26(a)(2)(B) and of the facts supporting those opinions. This disclosure is considerably less extensive than the report required by Rule 26(a)(2)(B). Courts must take care against requiring undue detail, keeping in mind that these witnesses have not been specially retained and may not be as responsive to counsel as those who have.
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> ...
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> A witness who is not required to provide a report under Rule 26(a)(2)(B) may both testify as a fact witness and also provide expert testimony under Evidence Rule 702, 703, or 705. Frequent examples include physicians or other health care professionals and employees of a party who do not regularly provide expert testimony. Parties must identify such witnesses under Rule 26(a)(2)(A) and provide the disclosure required under Rule 26(a)(2)(C). The (a)(2)(C) disclosure obligation does not include facts unrelated to the expert opinions the witness will present.

See Fed. R. Civ. P. 26 Advisory Comm. Notes (2010).

C. Treating Physician Disclosure and Report Requirements

In *Goodman v. Staples the Office Superstore, LLC*, 644 F.3d 817 (9th Cir. 2011), the Ninth Circuit addressed the application of Rules 26(a)(2)(B) and (C) to treating physicians. The court recognized, in *Goodman*, the general rule that a treating physician is a percipient witness of the treatment rendered, rather than an expert retained or specially employed to provide expert testimony. For this reason, a treating physician is ordinarily not subject to the written report requirements of

Rule 26(a)(2)(B). *Id*. at 824 (citing Fed. R. Civ. P. 26 Advisory Comm. Notes (1993)). However, "a treating physician is only exempt from Rule 26(a)(2)(B)'s written report requirement to the extent that his opinions were formed during the course of treatment." *Id*. at 826. A treating physician is still a percipient witness of the treatment rendered and may testify as a fact witness and also provide expert testimony under Federal Evidence Rules 702, 703, and 705.

IV. DISCUSSION

Biomet seeks to exclude some[2] of Dr. Blakey's case-specific expert opinions relevant to metallosis and causation, arguing that he did not form these opinions during the course of treating Hix (and Hix did not provide a Rule 26(a)(2)(B) report for Dr. Blakey), and because the opinions were not based upon sufficient facts or data.

Biomet points to Dr. Blakey's 2015 affidavit as establishing that Dr. Blakey formed an opinion of metallosis secondary to the M2a Magnum that caused Hix's pain and need for revision surgery. In that affidavit, Dr. Blakey states: "I performed a left side hip revision surgery on Mr. Hix due to pain in from [sic] metallosis, which was secondary to the Biomet M2a Magnum hip implant." Biomet does not point to any evidence that Dr. Blakey did not form this opinion in the course of treating Hix other than noting that Dr. Blakey acknowledged that an attorney may have helped prepare the affidavit in which Dr. Blakey disclosed this opinion.

In contrast, the medical records created by Dr. Blakey indicate his awareness that Hix had a metal-on-metal hip implant and was suffering pain in his left hip. Dr. Blakey informed Hix that the pain was probably due to metallosis but could also be due to infection. In a subsequent visit, Dr. Blakey informed Hix that he was fairly certain Hix did not have an infection. Dr. Blakey performed the revision surgery, noting both a preoperative and postoperative diagnosis of "painful left metal-

[2] The Court notes that these arguments contrast with Biomet's caption which suggest the motion was brought to generally exclude any testimony from Dr. Blakey.

on-metal total hip secondary to metallosis." Biomet has not shown that Dr. Blakey's expert opinions were formed outside the course of treating Hix.

Biomet also argues Dr. Blakey's metallosis opinion must be excluded because it was not based upon sufficient facts or data. Biomet notes that Dr. Blakey testified, in his deposition, that his *expert opinion* was based on the findings of pathology. Biomet also notes, however, that Dr. Blakey made the preoperative and postoperative *diagnoses* (recorded in the report of the revision operation) of metallosis before the pathology was done. Biomet asserts that this establishes Dr. Blakey made a faulty diagnosis. Whether Dr. Blakey's diagnosis of metallosis (as recorded in the revision operation report) is faulty because it was made prior to the pathology is an issue that goes to the weight, not the admissibility, of Dr. Blakey's expert opinion of metallosis. Biomet has not established that Dr. Blakey's opinion based upon the pathology is unreliable under *Daubert.*

CONCLUSION

IT IS HEREBY ORDERED that the Motion in Limine to Exclude Plaintiff's Case-Specific Expert Richard Blakey, M.D. brought by Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC. (ECF No. 274) is DENIED.

IT IS SO ORDERED.

Dated: March 29, 2022

ROBERT C. JONES
United States District Judge